IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 4 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS'MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT BRIAN PARKER, M.D.

Plaintiffs respectfully request that this Court exclude or otherwise limit the opinions and testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Brian Parker, M.D. ("Dr. Parker"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Parker is a board-certified Urologist from Knoxville, Tennessee. Plaintiffs do not challenge his qualifications as such. Dr. Parker is also a paid consultant for medical device manufacturers, including Coloplast, Medtronic and Galil Medical. *See* Exhibit D (Deposition of Brian Parker, M.D., 3/14/17, 6:6-12); *see generally* Exhibit B (Parker Report); and *see* Exhibit C (Parker curriculum vitae). He has been hired by Ethicon to prepare a general report on the GYNECARE TVT Obturator ("TVT-O") and TVT Secur ("TVT-S") mesh implant devices.

Dr. Parker's general report sets forth his opinions with regard to the TVT-O and TVT-S devices including opinions related to the adequacy of the warnings and IFUs, design and material properties of Ethicon's TVT, TVT-O, and TVT-S devices, complications associated with these

products compared to other surgical options to treat SUI conditions as well as all other opinions related to the design and performance of these products, positions statements concerning the safety of these devices made by professional societies or the FDA, and opinions that polypropylene sling products are the gold standard, standard of care or state of the art for treating stress urinary incontinence. Additionally, Dr. Parker offers opinions on the material properties of polypropylene mesh including degradation, cytotoxicity, contraction of mesh, adequacy of pore size and weight of the mesh, as well as a lack of clinical difference between laser and mechanically cut mesh.

As explained below, Dr. Parker is unqualified to offer many of these opinions as is evident in both his report and deposition testimony. Dr. Parker's experience in the field of Urology does not render all of his opinions admissible. Moreover, even assuming he has the requisite qualifications, these opinions are at best *ipse dixit* and should be excluded.

LEGAL STANDARD

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." F.R.E. 702. In the context of Rule 702, "'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993). Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the matters

upon which she will opine are clearly within her area of expertise." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D. N.C. 2007).

If the expert is qualified, "[t]he U.S. Supreme Court [has] established a two-part test to govern the admissibility of [the] expert testimony under Rule 702—the evidence is admitted if it 'rests on a reliable foundation and is relevant.'" *Tyree v. Boston Scientific Corp*., 54 F.Supp.3d 501, 516 (S.D. W. Va. 2014) (*quoting Daubert*, 509 U.S. at 597). Although "[t]he proponent of expert testimony does not have the burden to 'prove' anything to the court," he or she must nonetheless "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id*. (*quoting Md. Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided a non-exhaustive list of factors for a judge to consider in applying F.R.E. 702: "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper v. Smith & Nephew, Inc*., 259 F.3d 194, 199 (4th Cir. 2001) (*citing Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). "The inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (*quoting Daubert*, 509 U.S. at 594-95). Even so, "'[e]xpert witnesses have the potential to be both powerful and quite misleading[;]' the [trial] court must 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" *Tyree*, 54 F.Supp.3d at 516 (quoting Cooper, 259 F.3d at 199).

ARGUMENT

I. Dr. Parker's General Opinions Regarding the Adequacy of the Warnings and IFUs for the TVT-O and TVT-S Devices Should Be Precluded or Limited.

Dr. Parker lacks special qualifications in regulatory matters. *See* Exhibit D, at 80:23-84:20. As this Court has previously held, medical experts not qualified to offer opinions regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience. *See Sederholm v. Boston Scientific Corp.*, C. A. No. 2:13-cv-12510, 2016 WL 3282587 at *13 (S.D.W. Va. June 14, 2016)(excluding urologist's expert opinions on the adequacy of defendant's IFU that he based solely on the risks he observed in his practice.). In rendering his opinions regarding the TVT-O and TVT-S IFUs, Dr. Parker did not consult published standards governing the information that should be included in medical device warnings, nor is he familiar with the industry standards governing warnings on medical devices. *See* Exhibit D at 143:13-158:3. Dr. Parker's opinions regarding what he would consider to be an adequate warning are based solely on his personal experience. *Id*.

Moreover, in his report, Dr. Parker states that "Surgeons do not rely on product labeling from a company to understand the risks or complications that can accompany vaginal or pelvic floor surgery" and that "I also am of the opinion that the fact that Ethicon changed its product labeling in 2015 does not mean that the prior IFUs failed to identify risks that weren't commonly known by pelvic surgeons." *See* Exhibit B, at 11, 12, 16 and 17. Evidently, the basis for his opinions regarding the TVT-O and TVT-S IFUs are not that the IFUs sufficiently warned of all risks—but that in his personal experience the issue is irrelevant because doctors do not rely on the IFUs. *See* Exhibit B, at 17; Exhibit D at 145:10-146:1. Additionally, Dr. Parker also holds opinions with regards to all other materials used to train doctors on these devices, even though he

cannot say with certainty that he has reviewed all the available training materials and documents. *See Id.* at 96:21-98:11.

Dr. Parker has failed to offer this Court sufficient proof that the adequacy of the IFUs is within his area of expertise. He is neither familiar with the standards applicable to medical device IFUs nor the process by which IFUs are developed and approved. *See* Exhibit D at 143:13-158:3. He does not rely on any standards *nor* information from Ethicon in rendering his opinions regarding the TVT-O and TVT-S IFUs. Rather, he relies solely on his own personal opinion and experience. The United States Supreme Court, the Fourth Circuit and this Court have all expressly held that an opinion based on nothing more than the *ipse dixit* of the expert is inadmissible. *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* [an assertion made but not proved] of the expert"); *Cooper*, 259 F.3d at 202-03 (same); *Bourne v. E.I. Dupont de Nemours & Co., Inc*., 189 F. Supp. 2d 482, 499 (S.D.W. Va. 2002) (same); *see also Hoffman v. Monsanto Co.*, No. 2:05-CV- 00418, 2007 WL 2984692, *4 (S.D.W. Va. Oct. 11, 2007) (excluding an opinion that was based on "simply a subjective, conclusory approach that cannot reasonably be assessed for reliability") (*quoting* Fed. R. Evid. 702, advisory committee's note (2000)). This Court has previously rejected this "I have not seen any risks in my practice that were not in the defendant's product instructions, so therefore the instructions are adequate":

> Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Carl Sagan, The Demon-Haunted World: Science as a Candle in the Dark 213 (1996). Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because for the first time during these MDLs, the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product

> warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I FIND that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice.

Tyree v. Boston Scientific Corp., Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order). A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. General Motors Corp*., 190 F.3d 244, 250 (4th Cir.1999). Dr. Parker's opinions concerning the adequacy of the TVT-O and TVT-S warnings and IFUs are unreliable and should be excluded.

II. Dr. Parker's General Opinions on the Design and Scientific Properties of the TVT-O and TVT-S Devices Should Be Precluded or Limited.

Dr. Parker does not have any specialized education or training or applicable relevant experience specifically related to the design of polypropylene mesh devices. *See generally* Exhibits B and C. In fact, Dr. Parker readily concedes that he is not an expert in designing mesh devices and has limited knowledge of the design process:

> Q. Okay. So I guess what I want to get an understanding of is the opinions that you hold in your report. Are you an expert -- are you holding yourself out as an expert on the design of medical devices?

A. Only as they apply to how they are used when the final product is available and used on a patient. But the actual engineering, I wouldn't.

Q. So you've never designed a medical device in your practice?

A. No, but I have been involved with a think tank, help improve designs for the Medtronic Interstim device. I've helped with that, but I haven't physically engineered any type of sling device.

Q. Are you familiar -- as part of your review in offering these opinions, did you make yourself familiar with the standards a manufacturer must follow in designing a mesh product?

MR. WALKER: Object to form.

A. So you're asking me if there's a certain set of guidelines that manufacturers have to follow? No, I'm not aware of how that process goes on.

Exhibit D at 137:24-138:19. *See also Id*. at 138:20-143:7

Despite the fact that Dr. Parker admits he's not an expert on designing mesh devices, he attempts to opine on the design and material properties of the TVT-O and TVT-S devices, including the topics of degradation, cytotoxicity, mesh contraction, the appropriate pore size and weight of mesh, as well as differentiate between mechanical and laser cut meshes. *See* Exhibit B at 11, 15, 18-21. Specifically, his opinion in this regard is that the devices are "safe and effective and not defectively designed." Exhibit B at 11 (*See also Id*. at 15 regarding TVT-S). These opinions undoubtedly exceed the bounds of his qualifications.

Dr. Parker opines that the "hallmark of Prolene suture is that is a monofilament, and maintains its strength and does not degrade or become absorbable." Exhibit B at 18. He further states that "If there was ***substantial*** degradation, we would have already seen a clinical problem arise in not only one but likely all of these surgical disciplines." *Id.* (emphasis added). However,

on the issue of Degradation, including particle loss, Dr. Parker admits that he is not a biochemist and has not been involved in any studies that look at the pathology of removed mesh devices. *See* Exhibit D at 117:11-119:16, 186:16-188:3. As a matter of fact, the first time he learned that polypropylene could degrade was late last year when he began working on his general report. Exhibit D at 33:6-35:7. Dr. Parker's opinions relating to degradation, as set forth in his expert report and deposition testimony, appear to be based solely on his clinical experiences rather than education or training. He admits that anything he has read with regards to degradation would have been included in his reliance materials. Exhibit D at 168:5-20, *see also* Exhibit E (Parker Supplemental Reliance List).

The pertinent question to this analysis is not whether or not Dr. Parker is right or wrong. Plaintiffs do not need to challenge these opinions based on their accuracy. *See Westberry*, 178 F.3d at 261(the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.) The fatal flaw in Dr. Parker's opinions is that they appear to be primarily based on the premise that since he himself has not identified a clinical outcome that in his mind correlates with degradation, then the mesh must not be degrading. Although Dr. Parker claims to have reviewed the medical literature related to degradation that was provided by Ethicon and cited in his reliance list, he admits that his personal research merely involved "some PubMed searches that I did that I just kind of perused the abstract of. I didn't break down every bit of it. I just tried to learn a little bit more about what that was all about."

Under *Daubert*, a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation." *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 473-

74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method.) Simply because the selective documents provided by Ethicon do not address degradation and he chose to presumptively disregard any literature contrary to his opinion this does not allow Dr. Parker to testify in an expert capacity to an inference that degradation is not possible or if possible, does not have clinical significance. As such, Dr. Parker has not "come forward with evidence from which the court can determine" that he is qualified to testify regarding degradation and particle loss. *Tyree, supra*.

The same is true of his unsupported statement regarding cytotoxicity and whether or not polypropylene is actually inert. Exhibit B at 18-19. In addition to the lack of relevant qualifications noted above, Dr. Parker has admitted that he is not planning on testifying as an expert on the basic properties and how polymers are put together. *See* Exhibit D at 168:21-169:8.

With regards to contraction, Dr. Parker states in his report that he is aware of no clinical data to support the theory that polypropylene mesh contracts the way Plaintiffs suggest. Exhibit B at 19-20. He also states that "Clinically, I have removed sling mesh and noted no difference in its appearance at the time of removal as it did at the time of placement" and "I do believe that during the healing process, with proliferation of fibroblasts, that the disuse surrounding the sling will contract some, but his is normal, natural and expected result." *Id.* A doctor's personal experience claiming to have not seen evidence of mesh shrinkage or contracture cannot serve as a reliable scientific basis for rendering an expert opinion in Federal court that, i.e., tissue and the mesh within do not contract or "shrink" after implantation.

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (*quoting Daubert*, 509 U.S. at 593–94). *In re C.R. Bard, Inc. Pelvic Repair System Prods. Liab. Litig.*, 948 F.Supp.2d 589, 602 (S.D.W.Va.2013) (*citing Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993)). Dr. Parker's opinions purporting to deny that mesh shrinkage has any clinical effect fail under every one of these reliability factors. Such opinions are directly contrary to numerous published, peer-reviewed articles, which establish beyond reasonable scientific dispute the general acceptance of the phenomenon of in vivo mesh shrinkage. Dr. Parker's opinions regarding mesh contracture should be excluded.

Dr. Parker attempts to opine on the porosity and weight of the TVT-O and TVT-S mesh devices stating that in his medical opinion, the mesh is "macroporous and ideal for proper tissue integration" and that Plaintiffs' experts' attempts to classify the mesh as heavyweight mesh are unfounded. *See* Exhibit B at 20-21. According to his testimony, Dr. Parker only reviewed one document to gain his understanding of the pore size with regards to the TVT devices. *See* Exhibit D at 109:8-117:10. Dr. Parker's qualifications as a physician, even a physician specializing in pelvic floor surgery, are not sufficient to allow him to testify on design issues such as this. *Tyree v. Boston Scientific Corp.*, 2014 WL 5320566 (S.D.W. Va. 2014) (this Court excluded opinions by Dr. Jerry G. Blaivas, one of the plaintiff's experts, relating to the design of pelvic mesh products). These opinions undoubtedly exceed the bounds of his qualifications.

The same is true with regards to the differences between mechanically cut and laser cut mesh, Dr. Parker lacks any reliable basis to offer opinions about the differences and, in fact, was unaware of those differences:

Q. Doctor, are you familiar with the difference between mechanically-cut versus laser-cut meshes?

A. I am.

Q. Tell me what your understanding is of the difference between those two devices.

A. Well, one is actually physically cut with some type of shears or some type of device, and the other one is cut on the side with a laser to give you the device shape. I don't know anything more than that, though, how they do it.

Q. And have you implanted both types of mesh?

A. I assume I have. I know I have. I know I have because TVT-Secur is laser cut and the TVT-O is, for the most part, mechanically cut.

Q. Do you recognize any differences between the meshes, the two types of meshes, when you look at them or feel them?

A. I don't notice any differences when I feel them. The only difference you can see is when the laser has come across the edge, there may be more of a heat-sealed type of look on the side of it. But there's no -- other than that, they feel the same, they look the same, yeah. It's not something in residency or in training that has been brought up. But, yeah, I know now.

Q. Are you familiar with the differences in the type of adverse reactions that are associated between the two types of devices?

MR. WALKER: Object to form.

A. No. Honestly, I haven't seen anything

like that in the literature. It appears to me that the adverse events are about the same.

Exhibit D at 27:12-28:18.

Q. And if you look to page 21, laser-cut mesh versus mechanically-cut mesh, we talked about that briefly earlier. As far as your opinions here, you say that the mesh is not defective because of the way that it's cut. Can you tell us a little bit more about how you came to that conclusion?

A. Right. So if you look at studies from TVT-O, there's some TVT-O that's laser cut and some that's mechanically cut. Personally, I think if you polled most physicians, they wouldn't know the difference in what they were holding. But if you were to look at the studies to see if there was a difference, you're not going to find it. And so based on that, you have to then conclude that whether it's laser or mechanical cut, it's of no clinical difference. There's just no studies. There's nothing there to support it.

Q. As far as your review in preparing your opinions on that matter in this case, do you recall reviewing any documents, internal documents, from Ethicon that suggest that there was a concern –

A. Uh-huh.

Q. -- with regard to these differences and whether or not they actually did make a difference in the success rates or the safety profile of the product?

MR. WALKER: Object to form.

A. Yes, I do remember seeing internal documents and there were conversations. And I think those conversations had to be had because there was a difference. But, again, I'm looking at it from a perspective of is there any data to suggest there's a problem or a difference. And if there is, I'm not aware of it.
So conversations and those things have to take place within a company. I'm not worried about that. It doesn't change my viewpoint. And I actually applaud them for thinking outside the box. But I don't see that

19 it's been borne out in any literature.

Exhibit D at 174:9-175:19.

Aside from failing to offer the Court a basis for finding him qualified to testify on these matters, Dr. Parker also fails to provide a reliable basis for his opinions. He does not show that he utilized any method, much less a scientifically reliable method, for arriving at his opinions. Dr. Parker often states his opinions as conclusions with no supporting information and unaccompanied by any methodologically sound or scientific analysis. For example, Dr. Parker refers to Professional Society Statements as generally being viewed by practicing Urologists, Gynecologists, and Urogynecologists as a "beacon" upon which they can rely on to guide in clinical decision making. *See* Exhibit B at 13-14. In another example, Dr. Parker states that he would "still use TVT Secure today in my practice if it were available" stating that it is a distraction to focus on things that aren't "clinically relevant. *Id*. at 7. He goes on to state that "many studies done on numerous medications, implants, devices, materials, etc. which when taken in a vaccum can seem so heinous and critical, but when studies at a clinical level show no relevancy" suggesting that many studies, when looked at from the patient level, have no "real value." *Id.*

As this Court has observed, "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Tyree*, 54 F.Supp.3d at 520: (*quoting In re Rezulin Products Liab. Litig*., 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005) (quotations omitted)). Where, as here, the "relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" *Id*.

For the stated reasons, Dr. Parker's opinions regarding the material properties of polypropylene mesh including degradation, cytotoxicity, contraction of mesh, adequacy of pore size and weight of the mesh, as well as a lack of clinical difference between laser and mechanically cut mesh, should be excluded.

CONCLUSION

For these reasons, Plaintiffs ask that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Parker. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

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Dated: April 13, 2017

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document April 13, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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